REMARKS

Included herewith is a petition for a three month extension of time and authorization to charge our deposit account 19-0134. The time for response to the Office Action is now set to February 23, 2006.

Claims 7-22 are pending in this office action. Claims 8, 11-18, 21 and 22 stand rejected under 35 USC 112, first paragraph for lack of enablement. Claims 8, 11, 12, 16-18 and 21 stand rejected under 35 USC 102(b) as being anticipated by Boker, *et al.* Claims 7, 9, 10, 19 and 20 are allowable apart from the potential interference issues.

Rejection under 35 USC 112, first paragraph

The Examiner acknowledges the specification is enabling for treatment of herpes simplex virus infection but concludes the specification does not reasonably provide enablement for prophylaxis of herpesvirus infection. As is well established, a statement in the specification as broad as the broadest claim satisfies the enabling requirement unless (1) the Examiner properly challenges the truth of the statement (In re Marzocchi 169 USP 367) or (2) undue experimentation would be required to practice the invention as claimd (In re Borkowski 164 USPQ 642). The Examiner cites various abstracts and "limited teachings in the specification, and the absence of a working example" to support the conclusion that undue experimentation would be required to practice prophylaxis of herpes simplex virus infection.

It is submitted the specification provides sufficient guidance for a skilled artisan to practice the method. The claims are limited to two types of nucleoside analogs, i.e., famciclovir and penciclovir, which are well known in the art. Likewise, immunosuppressants suitable for use in Applicants' method are also well known in the art. Great detail regarding, *inter alia*, types of administration, dosing regimens and dosage forms is provided on pages 4-6 of the specification. Regarding embodiment of Applicants' method, it is stated on page 3, last paragraph of the specification that the active ingredient will be administered according to normal dosage and administration required for the ingredients alone. There is a high level of skill in the art at the time that the application was filed and prophylaxis methods are well known in the art.

Determining specific dosing regimens, specific dosage forms, etc. to practice Applicants' prophylaxis method requires only routine experimentation. It is submitted that any experiments requiring the practice of Applicants' prophylaxis method would not be particularly voluminous or complicated; however, the fact that the experimentation may be voluminous or complicated, still

does not make such experimentation undue if such experimentation is routine. As stated by the Federal Circuit:

> The test [for undue experiment] is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provide a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention.

Johns Hopkins University v. Cellpro, Inc. 47 USPQ2d 1705, 1719; quoting PPG Indus., Inc. v. Guardian Indus. Corp. 37 USPQ2d 1618, 1623. This concept is further illustrated by the Federal Circuit in In re Wands, supra where the process to practice the claimed invention required "immunizing animals, fusing lymphocytes from the immunized animals with myeloma cells to make hybridomas, cloning the hybridomas, and screening the antibodies produced by the hybridomas for the desired characteristics." (In re Wands at 1407) Just as in the case of In re Wands only conventional and well-known techniques would be required to practice Applicant's prophylaxis method.

Finally, attached herewith is a page copied from Webster's Dictionary providing a definition of prophylaxis. Prophylaxis as defined is a protected treatment for or prevention of disease. Applicants submit the prophylactic measures using the compounds of the invention are not limited to prevention of infection but are also to prevent development of infection or where the infection has already developed, to protect against worsening of the process. Clearly, in view of the foregoing arguments, one of skill in the art would know how to use the compounds of the invention for prophylactic treatment.

Rejection under 35 USC 102

Claims 8, 11, 12, 16-18 and 21 stand rejected under 35 USC 102(b) as being anticipated by Boker. The Examiner acknowledges Boker is silent on herpesvirus however, "since immunosuppressed patients are at risk for newly-transmitted infections or reactivation of latent infections, the treated person is seen as meeting the requirement for a human in need of prophylaxis of a *herpes simplex virus infection*"

Boker teaches treatment of hepatitis B. Hepatitis B is a disease caused by a virus that attacks the liver leading to liver disease and liver cancer. On the other hand, herpes simplex virus is a disease caused by a virus that attacks the mouth or genital areas including causing shingles or chickenpox. Its mechanism of action differs from Hepatitis B.

Applicants' invention is a pharmaceutical composition for oral or parenteral administration of famciclovir or penciclovir and an immunosuppressant to treat herpes simplex

virus. Nowhere in Bok is there mentioned such pharmaceutical as claimed to reduce herpes viral replication. As evidence, the examples in the specification describe that treatment of immunosuppressed mice with famciclovor had significantly greater effect on viral replication and the disease (see specification, page 7, lines 3-10). Bok does not anticipate because it has not met all elements of the claimed invention.

> Furthermore, MPEP Section 2112 states:
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> to establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted)

The Examiner has significantly extrapolated beyond the description of the Bok reference by concluding that the viral infections can be similarly treated. Here, the Examiner admits herpes virus is not taught in the reference. All viral infections are not the same.

The Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy,* 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) see MPEP 2112. As herein, where the viral infections are not similar, where there is no teaching of the invention as claimed and particularly where the reference is silent on the topic of herpes virus, the Examiner cannot rely on possibilities or probabilities that viral infections can be inherently treated the same way. It is submitted the Examiner has not met the burden of proof to establish inherency.

Interference

The Examiner has noted that the submitted claims may not be patentably distinct from US6337324 ('324). Specifically, the Examiner alleges topical administration by "creams, lotions, gels, ointments or drops" in '324 cannot be distinguished from Applicants' disclosure of oral administration in the form of "solutions, syrups and suspensions". Specifically, the Examiner alleges no distinction between "drops" and "solutions, syrups and suspensions". Further, regarding Applicants' parenteral administration, the Examiner notes there does not appear to be any physical or chemical feature distinguishing "creams, lotions, gels, ointments" disclosed '324 with "emulsions in oily or aqueous vehicles" in the specification or "drops" in '324 and "suspensions and solutions" in the specification.

Applicants respectfully disagree. The terms referred to above are commonly used in the formulation art. One of skill in the art would know that drops would not typically be understood

to include oral administration. The logistics of taking a sufficient number of drops to administer the drug seems counterintuitive and certainly inconvenient. On page 4, lines 9-10 parenteral administration is disclosed as intramuscularly or more particularly intravenously. The Examiner's proposal that the "creams, lotions, gels, ointments" might be administered intramuscularly or intravenously (i.e., parenterally) is again not typically used in the formulation art. One of skill in the art would understand what parenteral formulation would be acceptable to the patient and the FDA and would not get creams confused with intravenous formulations.

Regarding the Examiners allegations that the oral methods claimed are not distinguishable from the patent claims directed to "mucous membranes" in '324, it is noted that the claims of '324 are directed to topical administration. Col. 5, lines 41-55 define topical administration by creams, lotions, gels, ointments or drops which "can be incorporated into plaster or patches to be applied to the skin of a patient". The reference to "mucous membrane" in '324 refers to "pens or sticks". The specification, on the other hand, discloses on page 4, lines 21-30 that oral use includes tablets, capsules and liquids. None of which can be interpreted to mean a cream, lotion, gel, ointment, pen or stick which is applied onto skin or mucous membrane as the Examiner would have it.

However, in order to advance prosecution, Applicants have added claims which were deemed by the Examiner to be distinct from the patent.

Respectfully submitted,

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